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EXAMINER

JIANG, SHAOJIA A

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 01/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/058,299

Applicant(s)

NEWMARK ET AL.

Examiner

Shaojia A. Jiang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 13-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

***Election/Restrictions***

Applicant's election without traverse of the invention of Group I, Claims 1-12, in Paper No. 5, submitted October 23, 2002 is acknowledged.

It is noted that in the Restriction Requirement mailed September 23, 2002, "Claims 1-13" drawn compositions herein is merely an oversight.

Claims 13-24 drawn to a method herein are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling for the particular extract of turmeric disclosed in the specification in compositions herein, does not reasonably provide enablement for the employment any supercritical extracts.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required

undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApl's 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence of absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art
- 7) the predictability of the art, and
- 8) the breadth of the claims.

In the instant case, "a **supercritical** extract" may encompass any supercritical extract. Moreover, it is unclear what is "a **supercritical** extract". Thus, the specification fails to provide sufficient working examples to support the broad use of any "supercritical extracts" in the claimed compositions. Note that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 166 USPQ 18 indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Hence, the instant claims read on the employment of any "supercritical extracts" in pharmaceutical composition to be administered to a human, necessitating one of skill to perform an exhaustive search for the embodiments of any "supercritical extracts" suitable to practice the claimed invention.

Therefore, in view of the Wands factors, e.g., the amount of direction or guidance provided, absence of working examples, and the predictability of the art, Applicants fail to provide information sufficient to practice the claimed invention absent undue experimentation.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to the employment of a combination of active agents in "synergistic in combination" (see instant claim 5). The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,

- 3) the presence or absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art
- 7) the predictability of the art, and
- 8) the breadth of the claims.

Synergistic or superadditive effects for combinations of compounds are highly unpredictable. In the instant case there is no guidance or working examples in the specification showing amounts and particular agents to be combined which achieve synergistic effects by the turmeric composition in combination with green tea for effecting smoke detoxification.

Therefore, in view of the unpredictability of such synergistic effect of the claimed combination, the guidance in the specification is considered insufficient to show one of skill in the art how to practice the claimed invention without undue experimentation.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "**sup rcritical**" in claims 1-12 renders claims 1-12 indefinite. The expression "**supercritical**" is not defined in the specification. Therefore, the claims are unclear as to what may be considered as "a **supercritical** extract".

The expression "a...period of time" in claim 6 renders claim 6 indefinite. The expression " a...period of time " is not defined in the specification. Therefore, the claims are unclear as to how long may be considered as "a...period of time".

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Majeed et al. (5,861,415, PTO-892).

Majeed et al. discloses a composition comprising an extract of turmeric including at least one of curcuminoids. See abstract and col. 2 lines 36-40. Majeed et al. also discloses that methanol, a known hydroalcoholic solvent, is used in the extract process (see col. 6 lines 30-31 and claim 3). Thus, Majeed et al. anticipates the claims 1 and 3.

Applicant is requested to note that "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious

from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). The product-by-process claim was rejected because the end product. See MPEP 2113.

Applicant is further requested to note that it is well settled that “intended use” of a composition or product, e.g., effect smoke detoxification in a human, will not further limit claims drawn to a composition or product. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 5, even though it is not anticipated by Majeed et al. (5,861,415, PTO-892) as applicable to claims 1 and 3, is rejected under 35 U.S.C. 103(a) as being unpatentable over Majeed et al. (5,861,415) and “Antioxidant Effects of Tea”(page 249-254) or Applicant’s admission regarding the prior art in the specification (see page 5 lines 4-6).

Majeed et al. discloses that an extract of turmeric containing curcuminoids is known antioxidants and all curcuminoids show excellent antioxidant activity. Therefore,



curcuminoids in the extract of turmeric are useful in a pharmaceutical composition to be administered as antioxidants. See abstract, col.1 lines 23-24, and col. 2 lines 23-24 and 36-40. Majeed et al. also discloses that methanol, a known hydroalcoholic solvent, is used in the extract process (see col. 6 lines 30-31 and claim 3).

The prior art does not expressly disclose the composition of Majeed et al. further comprising an aqueous extract of green tea.

"Antioxidant Effects of Tea"(page 249-254) or Applicant's admission regarding the prior art in the specification (see page 5 lines 4-6) teaches that green tea is also known to have antioxidant activity.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ an aqueous extract of green tea in combination with an extract of turmeric containing curcuminoids in the composition of Majeed et al.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ an aqueous extract of green tea in combination with an extract of turmeric containing curcuminoids in the composition of Majeed et al. since both an extract of turmeric containing curcuminoids and an aqueous extract of green tea are known antioxidants and also known to be useful in a pharmaceutical composition to be administered as antioxidants. Therefore, one of ordinary skill in the art would have reasonably expected that combining an extract of turmeric containing curcuminoids and an aqueous extract of green tea known useful for the same purpose, i.e., being antioxidants, in a composition to be administered would produce additive therapeutic effects in antioxidant activity.

Since all active composition components herein are known to be useful to treat and prevent Alzheimer's disease, it is considered *prima facie* obvious to combine them into a single composition to form a third composition useful for the very same purpose. At least additive therapeutic effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

Thus the claimed invention as a whole is clearly *prima facie* obvious over the combined teachings of the prior art.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oppenheim et al. (WO 99/20289, PTO-892) and "Antioxidant Effects of Tea" (page 249-254) or Applicant's admission regarding the prior art in the specification (see page 5 lines 4-6).

Oppenheim et al. discloses that a clear herbal extract composition may comprise an extract of turmeric containing curcuminoids, an extract of green tea, an extract of parsley seed, an extract of rosemary, and an extract of ginger. See page 6-9. Oppenheim et al. also discloses extraction processes for herbal plants using a variety

of extracting solvents such as water and ethanol (see page 1 lines 15-25, and page 3 lines 14-22).

The prior art does not expressly disclose the effective amounts of active agents in the composition herein to be administered.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to optimize the effective amounts of active agents in the composition herein to be administered.

One having ordinary skill in the art at the time the invention was made would have been motivated to optimize the effective amounts of active agents in the composition herein to be administered because the optimization of amounts of active agents to be administered is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,391,364.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent is drawn to a composition comprising a hydroalcoholic of turmeric in an effective amount. The claim of the instant application is also drawn to a composition comprising a hydroalcoholic extract of turmeric in an effective amount. Therefore, one of ordinary skill in the art would have found that the instant composition is clearly obvious in view of the patent 6,391,364.

Claims 1-4 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,264,995.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent is drawn to a composition comprising a hydroalcoholic or supercritical carbon dioxide extract of of turmeric in an effective amount. The claim of the instant application is also drawn to a composition comprising a hydroalcoholic of turmeric in an effective amount. Therefore, one of ordinary skill in the art would have found that the instant composition is clearly obvious in view of the patent 6,264,995.

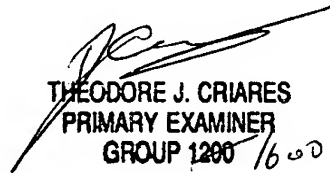
In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.  
Patent Examiner, AU 1617  
December 31, 2002

  
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